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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/910,198	07/20/2001	Steven P. Sidwell	2758	1473
7590	06/01/2004		EXAMINER	
BELLA FISHMAN VARIAN, INC. 3120 HANSEN WAY, D-102 PALO ALTO, CA 94304-1030			NGUYEN, BAO THUY L	
			ART UNIT	PAPER NUMBER
			1641	

DATE MAILED: 06/01/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

<b>Office Action Summary</b>	<b>Application No.</b> 09/910,198	<b>Applicant(s)</b> SIDWELL ET AL.	
	<b>Examiner</b> Bao-Thuy L. Nguyen	<b>Art Unit</b> 1641	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

#### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

#### Status

- 1) ☒ Responsive to communication(s) filed on 26 March 2004.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

#### Disposition of Claims

- 4) ☒ Claim(s) 1-20 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-20 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

#### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

#### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.

#### Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)  
Paper No(s)/Mail Date \_\_\_\_\_.
- 4) ☐ Interview Summary (PTO-413)  
Paper No(s)/Mail Date. \_\_\_\_\_.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: \_\_\_\_\_.

### **DETAILED ACTION**

1. Applicant's amendment dated 3/26/2004 has been received. Claims 21 and 22 have been cancelled. Claims 1-20 are pending.
2. The text of those US Codes not found in this office action may be found in a previous office action.

#### ***Claim Rejections - 35 USC § 112***

3. Claim 10-11 rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 10 is confusing because it is unclear how a "transparent film" is able to change the white strip to a color. There is no recitation of the film being a colored film. Therefore, it has been interpreted as a clear, transparent film, as such, it is unclear how is clear, transparent film can change the color of a white strip to a color that can enhance visual perception.

#### ***Claim Rejections - 35 USC § 102***

4. Claims 1, 2, 8, 9, 10, 11, 16, 17, 18 are rejected under 35 U.S.C. 102(b) as being clearly anticipated by Chandler (US 5,877,028).

Chandler discloses a chromatographic assay device for use with immunoassays. The device comprises: (1) a first opposable component comprising a sample preparation zone adapted to receive a sample to be assayed, and (2) a second opposable component comprising a chromatographic medium. The first and second opposable components can be brought into opposition so as to cause the sample preparation zone to apply the sample to be tested to the

chromatographic medium. Preferably, the analyte is detected with a visually detectable label. See column 18. Chandler also teaches that the labeled specific binding partner can be present on an element of the chromatographic assay device that is separate from the sample preparation zone but comes into contact with it during the performance of the assay. See column 22, line 61 through column 23, line 4. Chandler teaches that a flexible transparent support is placed on top of the chromatographic medium to regulate the flow of the sample through the membrane and prevent migration over the top of the membrane. Suitable flexible transparent supports include polyethylene, vinyl, Mylar® and cellophane. See column 23, lines 21-26. In one specific embodiment, Chandler teaches that an inert dye is used to monitor the flow of the sample through the chromatographic medium. Specifically, the inert dye is of a contrasting color to that of the detectable label. For example, when the detectable label is pink colloidal gold, the inert dye can be blue. See column 34, lines 40-64.

#### ***Response to Arguments***

5. Applicant's arguments filed 3/26/2004 have been fully considered but they are not persuasive.

Applicant argues that the Chandler reference fails to teach or suggest a means for providing a complimentary color background for the colored site in order to increase visual perception of the colored site. Instead, Chandler teaches that an inert dye of a contrasting color is provided so that the flow of the sample through the chromatographic medium can be visually monitored. Applicant argues that this is not a teaching of the use of a complimentary color in order to increase visual perception of a colored site.

Applicant also argues that Chandler teaches away from the present invention since after a sample has migrated a sufficient distance, for example,  $2/3$  or  $3/4$  of the length of the chromatographic medium, the first and second opposite components are brought into opposition and the absorber is brought into contact with the first applicator. This reverses the flow of the sample through the chromatographic medium 346, allowing additional capture of the analyte at the detection zone 356. Therefore, applicant argues that there is no teaching of using color dye at the detection zone in order to increase visual perception.

These arguments have been fully considered but are not deemed to be persuasive. Even though Chandler does not specifically state that the inert dye is used to enhance visual perception at the detection site, Chandler does teach a means for changing the background color at the detection site. This means is the same as that recited in the claim and the specification, for example, a dye. Therefore, such a means inherently possesses the same function as those of the claim, i.e. when present at the detection site it provides an increase in visual perception. Specifically, Chandler teaches that the inert dye is selected so that it provides a contrasting color to that of the detectable label. For example, when the detectable label is pink colloidal gold, the inert dye is blue, two colors that are opposite on a color wheel.

Applicant argues that because Chandler teaches the reversal of liquid flow there is no teaching of using color dye at the detection zone. This argument is not persuasive because the sample along with the dye migrate pass the detection zone with the dye providing a color that contrasts the label at the detection site. Any action by the absorber to pull liquid in the reverse direction does not necessarily means that the chromatographic medium becomes clear or loses its color after having been "dyed".

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6. Applicant's argument with respect to the May reference has been fully considered and upon reconsideration, the rejection of claims 1-5, 8-13 and 16-18 is withdrawn. Applicant is correct in that May does not specifically teach a means for providing a complimentary color background. Even though May teaches the use of inert dye as disclosed in claim 2, the inert dye taught by May is present in the control zone only and does not appear to affect the detection zone.
7. Applicant's argument with respect to the rejection of claims 6, 7, 14, 16 19 and 20 over Chandler in view of Ogawa has been fully considered and the rejection is withdrawn. Even though Chandler and Ogawa teach using contrasting colors as labels and background for enhancing detection, both Chandler and Ogawa fail to specifically teach the specific color schemes as claimed.

*Allowable Subject Matter*

8. Claims 3-7, 12-15, 19 and 20 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

The following is a statement of reasons for the indication of allowable subject matter: the prior art of record fail to teach a lateral flow immunoassay device having a transparent colored film disposed over the porous strip to provide a complimentary color background for the detection site in order to increase visual perception of the detection site.

The prior art of record also fail to specifically teach using specific color schemes such as those in claims 6, 7, 14, 15, 19 and 20. Even though Chandler teaches the use of contrasting colors as label and background material, Chandler fails to specify these color schemes.

*Conclusion*

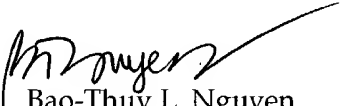
9. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure.

Lee-Own (US 5,500,375) teaches a device comprising a membrane covered with transparent plastic overlay by a layer of opaque material (white or colored plastic, tape, card, paper, paint, or pigments, etc) attached directly over the transparent plastic by adhesive, leaving suitable windows for viewing results, i.e. the viewing window is not covered by colored plastic. Although Lee-Own teaches that the detection zone contains label such that there is a contrast between the label and the membrane strip, Lee-Own also teaches that is contrasting phenomenon is used to indicate the presence or absence of the analyte in the detection zone and not for enhancing visual perception of the result. For example, a contrasting signal indicates the presence of analyte and a non-contrasting signal indicates the absence of the analyte. Lee-Own also teach an embodiment where in the absence of analyte, labeled reagent binds to the binding partner in the detection zone causing the contrast between the label in the detection zone and the membrane strip to disappear, and in the present of the analyte, the contrasting signal remains.

10. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Bao-Thuy L. Nguyen whose telephone number is (571) 272-0824. The examiner can normally be reached on Tuesday and Thursday from 9:00 a.m. - 4:30 p.m..

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Long V. Le can be reached on (571) 272-0823. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

  
Bao-Thuy L. Nguyen  
Primary Examiner  
Art Unit 1641

27 May 2004